

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Kastenmayer, et al.
Appl. No.: 10/523,767
Conf. No.: 7519
Filed: February 7, 2005
Title: CALCIUM ABSORPTION ENHANCER
Art Unit: 1784
Examiner: Hong T. Mehta
Docket No.: 3712036-00444

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated October 28, 2010 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the final Office Action dated April 19, 2010, as noted in Appellants' Appeal Brief filed on October 4, 2010, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejection of pending Claims 1, 3, 6-11 and 26-27 be reversed.

II. THE REJECTION OF CLAIMS 1, 3, 6-11 AND 26-27 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the rejections of Claims 1, 3, 6-11 and 26-27 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that skilled artisan would have no reason to combine the cited references to arrive at the present claims.

1. *Kaisha, Shlyankevich and Kirschmann* Fail to Disclose or Suggest Each and Every Element of the Present Claims

In the Examiner's Answer, the Examiner tacitly admits that the cited references fail to disclose or suggest the presently claimed ratio of egg whites to calcium. See, Examiner's Answer, page 8. However, the Examiner states that the "value [of 19] is so close to the value range claimed (20-60) so as to be considered not patentably distinguished from the prior art and is considered *prima facie* obviousness." See, Examiner's Answer, page 8, lines 9-11. The Examiner arrives at the value of 19 by providing a calculation of the ratio of egg whites to calcium of the cookie dough of *Kaisha* using the information disclosed in *Kirschmann*. See, Examiner's Answer, pages 6-7. Appellants respectfully disagree with the Examiner's rationale for at least the reasons set forth below.

As noted by the Examiner, independent Claims 1 and 6 recite, in part, calcium absorption enhancers comprising a ratio of egg white/calcium between 20 to 60 by weight. Appellants have found that giving calcium and/or isoflavones in parallel with egg white considerably enhances calcium absorption. See, Preliminary Amendment, page 8, lines 10-16. Although not wishing to be bound by theory, Appellants believe that the enhanced calcium absorption resulting from administration of the present compositions may be due to egg whites and isoflavones stabilizing the emulsion of calcium, preventing it from precipitating, or egg whites transformed into peptides during digestion, and these peptides help to keep calcium soluble in the intestine. See, Preliminary Amendment, page 8, lines 10-16. In contrast to the Examiner's assertion that no

evidence of such results has been presented, evidence of such effects is described in the Examples of the specification. Specifically, the Examples demonstrate that animal models of menopausal bone loss, daily consumption of soy isoflavones and egg whites enhanced calcium balance compared to controls. See, specification, Examples.

As such, Appellants respectfully submit that there exists a reason for the presently claimed ratio of egg white to calcium. Even assuming that *Kaisha* discloses an egg white to calcium ratio of 19, which Appellants submit has not been sufficiently demonstrated by the Examiner, as will be discussed further below, the references still fail to disclose even the lower most range limitation presently claimed by Appellants. Indeed, although the lower most range limitation for the presently claimed egg white/calcium ratio is 20, the range extends up to 60. The cited references fail to disclose or suggest any ratio that is included in the presently claimed ratio, let alone a ratio value that even comes close to the upper most range limitation.

Further, Appellants respectfully submit that the Examiner has failed to demonstrate that *Kaisha* discloses an egg white to calcium ratio of 19. For example, the Examiner cites *Kirschmann* for the disclosure of the weight ratios of egg white and yolk in eggs. The Examiner states that *Kirschmann* discloses that an egg comprises 31 grams of whites and 17 grams of yolk and then concludes that the egg of *Kirschmann* comprises 48 grams. However, the data in *Kirschmann* fails to identify what type of egg is being measured, whether the egg whites and yolk come from the same egg source, whether the size of the egg white egg is the same as the size of the yolk egg, whether the eggs include shells or not, etc., all of which can affect the significance of the weight measurements. As such, Appellants respectfully submit that the Examiner has failed to sufficiently demonstrate that *Kaisha* discloses the presently claimed egg white/calcium ratio.

Instead, and at best, *Kaisha* discloses a food/drink containing casein phosphopeptide ("CPP") and calcium to promote absorption of calcium. See, *Kaisha*, English translation Abstract. *Shlyankevich* is entirely directed to pharmaceutical compositions and dietary soybean food products for the prevention of osteoporosis. See, *Shlyankevich*, Abstract. *Kirschmann* is entirely directed to a Nutritional Almanac that provides nutritional information for various foods including, for example, cream, eggs, milk, fish, shrimp, etc. At best, *Kirschmann* discloses the content of the essential amino acids in egg whites. See, *Kirschmann*, page 239.

For at least the reasons set forth above, Appellants respectfully submit that the cited references fail to disclose each and every element of the present claims and, as such, that the Examiner has failed to establish a *prima facie* case of obviousness.

Accordingly, Appellants respectfully request that the obviousness rejection of Claims 1, 3, 6-11 and 26-27 be reconsidered and withdrawn.

2. The Skilled Artisan Would Have No Reason to Combine the Cited References to Arrive at the Present Claims

Although the Examiner tacitly admits that the cited references fail to disclose or suggest each and every element of the present claims, the Examiner continues to assert that “[i]t would have been obvious to one of ordinary skill to adjust or optimize the amount of egg whites in the baked goods of *Kaisha* depending upon the desired consistency and texture in the final product” and that the value of 19 for an egg white/calcium ratio “is so close to the value range claimed (20-60) so as to be considered not patentably distinguished from the prior art.” See, Examiner’s Answer, page 8. Appellants respectfully disagree and submit that the skilled artisan would have no reason to combine the cited references in the absence of hindsight because the cited references are directed to unrelated products that have completely different objectives.

For example, *Kaisha* discloses food/drink containing CPP to promote the absorption of calcium in a person having low calcium absorption ability. Although *Kaisha* discloses the use of CPP and calcium, *Kaisha* fails to disclose or suggest any isoflavone. Moreover, *Kaisha* fails to disclose the advantageous properties of either egg white or isoflavones for enhancing calcium absorption.

Shlyankevich discloses the use of a soybean diet for prevention of osteoporosis. Nevertheless, *Shlyankevich* fails to disclose the use of any egg white or the advantageous properties of egg white for enhancing calcium absorption. *Kirschmann* discloses the weight of specific egg components/products and does not teach or suggest any advantage for using egg whites with respect to calcium absorption.

Indeed, none of the cited references teaches or suggests the use of egg white in combination with isoflavones or at the claimed ranges for enhancing calcium absorption. Rather, at most, *Kaisha* discloses the use of CPP and calcium, while *Kirschmann* merely discloses egg

white to list essential amino acids associated with it. Based on *Kaisha*, *Shlyankevich* and *Kirschmann*, the skilled artisan would have no clue that egg whites in combination with isoflavones can be used to enhance calcium absorption, and would have no reason to “optimize” the weight ratio of egg white/calcium between 20 to 60 in accordance with the present claims. In addition, based on the cited references, the skilled artisan would have no reason to believe that the combination of egg white and an isoflavone can be used to significantly enhance calcium absorption in accordance with the present claims. As such, the compositions of the cited references are directed toward completely unrelated products having completely unrelated objectives. Accordingly, the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). This certainly applies here, where the primary reference is directed toward food/drink products having casein phosphopeptides and calcium and the secondary references are directed to pharmaceutical compositions having soybeans and the amino acid content of various foods, respectively.

Moreover, Appellants respectfully submit that what the Examiner has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Appellants also submit that if it were proper for the Examiner to simply pick any claim element from any prior art reference to arrive at the present claims simply because the reference suggests the element, then every invention would effectively be rendered obvious. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellants respectfully submit that such a reason is not present in the instant case.

For at least these reasons, Appellants respectfully submit that the obviousness rejection of Claims 1, 3, 6-11 and 26-27 is improper.

Accordingly, Appellants respectfully request that the obviousness rejection of Claims 1, 3, 6-11 and 26-27 under 35 U.S.C. §103(a) to *Kaisha*, *Shlyankevish*, and *Kirschmann* be reconsidered and withdrawn.

III. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the indefiniteness and obviousness rejections with respect to Claims 1, 3, 6-11 and 26-27.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00444 on the account statement.

Respectfully submitted,

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